Detailed Action

(1) The Examiner acknowledged the Amendment and Declarations filed in response to the last Office Action. However, the Examiner stated that the Declarations, which were misdesignated as being submitted pursuant to 37 C.F.R. § 1.132, were insufficient to overcome the rejection. The Examiner further stated that the Declarations would be reconsidered when applicants explain how the claims distinguish over the cited references as required by 37 C.F.R. § 1.111(c).

The Examiner is believed to have misunderstood the nature of the declarations and, therefore, is requested to reconsider them for the following reasons:

First, 37 C.F.R. § 1.111(c), cited by the Examiner, refers to arguments made with respect to amended claims. In applicants' prior response, the claims were not amended to overcome the prior art. Therefore, applicants should not be required to comply with the regulation.

Second, the Examiner referred to one Declaration Under 37 C.F.R. § 1.132. However, in fact, there are two declarations and they are Declarations under 37 C.F.R. § 1.131, not 1.132.

Importantly, section 715 of the MPEP discusses an Examiner's response to Declarations under 37 C.F.R. § 1.131 and expressly states that if the Examiner rejects the Declaration as being ineffective to overcome the reference, the Examiner must give at least one or several reasons explaining precisely why the Declaration is believed ineffective. The Examiner has not provided any such reasons. The Examiner did not explain why the declarations are believed inadequate or ineffective to overcome the references. Therefore, the Examiner did not provide a sufficient response to applicants' submission.

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Response under 37 C.F.R. § 1.116 U.S. Serial No. 09/214,155

Accordingly, the Examiner is requested to reconsider the 131 Declarations and provide an appropriate response as required by the MPEP.

Furthermore, if the claims are not allowed, the Examiner is requested to issue a new non-final Office Action, in order to give applicants a chance to respond to any explanation of inadequacies that should have been provided in the present Office Action.

(2) The Examiner required applicants to disclose all pending applications and/or patents related to the subject matter of this application.

Applicants advise that there are no other pending United States applications with related subject matter owned by the same assignees.

However, applicants are aware of three International Publications to another assignee, but having common inventors with this application.

They are as follows:

1. WO 00/66548 (US2003022872);

2-ALKYLATED VITAMIN D DERIVATIVES;

CHUGAI SEIYAKI KABUSHIKI KAISHA;

Inventor(s): Hiroaki TAKAYAMA, Toshie FUJISHIMA, Zhaopeng LIU, and NNO;

Katsuhiro KONNO;

Application No. JP99/5778, Filed October 20, 1999, Al Published November 9,

2000;

Vitamin D_3 derivatives which are substituted at the 2-position and epimerized at the 20-position and have -O- or -CH(CH₃)- at the 22-position, as represented by general formula (1): wherein X is -O- or -CH(CH₃)-; R^1 is a C_1 - C_{15} saturated or unsaturated aliphatic

Response under 37 C.F.R. § 1.116 U.S. Serial No. 09/214,155

hydrocarbon group which may be substituted with one to three optionally protected hydroxyl groups; and R^2 is a lower alkyl.

2. WO 01/16099

VITAMIN D DERIVATIVES HAVING SUBSTITUENTS AT THE 2α -

POSITION;

CHUGAI SEIYAKU KABUSHIKI KAISHA;

Inventor(s): Hiroaki, TAKAYAMA, Toshie FUJISHIMA, Yoshitomo SUHARA, Ken-ichi NIHEL and Katsuhiro KONNO;

Application No. JP0005743, Filed August 25, 2000, A1 Published March 8, 2001;

Vitamin D_3 derivatives having substituents at the 2α -position, which are represented by a general formula (I), wherein R^1 is a saturated aliphatic C_1 - C_{15} hydrocarbon group which may be substituted with one to three optionally protected hydroxyl groups; and R^2 is a saturated aliphatic C_1 - C_{10} hydrocarbon group optionally substituted with one or more members which may be the same or different from each other and are selected from among hydroxyl, halogeno, cyano, lower alkoxy, amino, and acylamino, with the proviso that when R^2 has only one carbon atom, it must have a substituent.

3. WO01/62723;

VITAMIN D DERIVATIVES HAVING SUBSTITUENTS AT THE 2 $\alpha\textsc{-Position};$

CHUGAI SEIYAKU KABUSHIKI KAISHA

Inventor(s): Hiroaki TAKAYAMA; Atsushi KITTAKA; Yoshitomo SUHARA and Toshie FUJISHIMA;

Response under 37 C.F.R. § 1.116 U.S. Serial No. 09/214,155

Application No. JP0101451, Filed October 27, 2001, A1 Published August 30,

2001;

The invention aims at synthesizing novel vitamin D derivatives having substituents at the

2 α-position. Vitamin D derivatives of a general formula (1) are provided wherein R₁ and R₂ are

each straight-chain or branched lower alkyl which may be hydroxylated.

Copies of the three above referenced documents along with a PTO Form 1449 listing the

references, are submitted herewith for the Examiner's convenience.

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

Registration No. 30,951

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Date:

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